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EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,372	CHRISTAKIS ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 January 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20010402*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: items 100 & 105 (Fig.1), items 200, 205, 210, 215, and 225 (Fig. 2), item 300 (Fig. 3), items 400 & 499 (Fig. 4), items 900 & 940 (Fig. 9), item 1000 (Fig. 10), and item 1100 (Fig. 11). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because its length exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-16 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 15-16 and 36 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) “the present prescription”: claim 15, line 2

(ii) “the dose”: claim 12, line 2 and claim 36, line 2.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-19, 22-51, and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Schrier et al. (5,833,599).

(A) Referring to claim 1, Schrier discloses a computer based method of providing evidence-based information to a service provider that is in the process of making a decision as to a treatment regimen to be followed, the method comprising the steps of (Fig. 1, item 110, col. 4, lines 24-27, and col. 3, lines 36-39 of Schrier; the Examiner interprets "clinician" to be a form of "service provider" and "drug information and dosing recommendations" to be a form of "treatment regimen to be followed"):

(a) prompting the provider to select a medication (col. 2, lines 23-33 of Schrier; the Examiner interprets "drug" to be a form of "medication");

(b) receiving the provider's selection of a medication (col. 2, lines 56-63 of Schrier); and

(c) in response to the provider's selective request, providing evidence-based information on the selected medication on a scaled basis (col. 3, lines 39-48 of Schrier; the Examiner interprets "publication references" to be a form of "evidence-based information").

(B) Referring to claim 2, Schrier discloses further comprising the steps of:

after step (b) and before step (c), prompting the provider to select an indication that is treatable using the selected medication; and

receiving the provider's selection of an indication;

wherein step (c) comprises providing evidence-based information on the selected medication as applied to treat the selected indication (col. 2, lines 40-43 and col. 3, lines 39-48 of Schrier; the Examiner interprets "clinical condition" to be a form of "indication" and "publication references" to be a form of "evidence-based information").

(C) Referring to claim 3, Schrier discloses wherein the step of prompting the provider to select an indication comprises providing a list of indications predetermined to be associated with the selected medication (col. 2, lines 40-43 of Schrier; the Examiner interprets "designate" to be a form of "select").

(D) Referring to claim 4, Schrier discloses further comprising the steps of:

before step (a), prompting the provider to select a condition of a patient to be treated (col. 8 lines 36-48 of Schrier); and

receiving the provider's selection of a condition (col. 5, lines 45-52 of Schrier);

wherein step (a) comprises providing a list of medications predetermined to be associated with the selected condition, from which the provider is prompted to select one medication (col. 5, lines 53-61 of Schrier).

(E) Referring to claim 5, Schrier discloses wherein the step of prompting the provider to select a condition comprises providing a list of predefined conditions, from which the provider is prompted to select one condition (col. 5, lines 45-52 of Schrier).

(F) Referring to claim 6, Schrier discloses further comprising the step of:

after step (b) and before step (c), presenting a summary of the evidence-based information on the selected medication to assist the provider in selectively requesting

the evidence-based information on a scaled basis (col. 29, line 63 – col. 30, line 1 of Schrier).

(G) Referring to claim 7, Schrier discloses wherein the evidence-based information comprises an article, and step (c) comprises the steps of:

presenting an at least one line summary of available evidence-based information;

presenting a synopsis of the article in response to a first request by the provider;

presenting an abstract of the article in response to a second request by the provider; and

presenting the article itself in response to a third request by the provider (col. 29, line 50 – col. 30, line 1 and col. 3, lines 46-48 of Schrier; the Examiner interprets "summary" to be a form of "abstract" and "synopsis").

(H) Referring to claim 8, Schrier discloses wherein the evidence-based information is stored in a predefined database (col. 29, lines 50-66 of Schrier).

(I) Referring to claim 9, Schrier discloses which is implemented on a network (col. 15, lines 41-46 of Schrier).

(J) Referring to claim 10, Schrier discloses wherein the evidence-based information is retrieved over a network (col. 15, lines 41-46 of Schrier).

(K) Referring to claim 11, Schrier discloses wherein the network is the Internet (col. 29, lines 53-55 of Schrier; the Examiner interprets "online" to be a form of "Internet").

(L) Referring to claim 12, Schrier discloses further comprising the step of prompting the provider to store, print, or forward to a designated location over a network the provided evidence-based information (col. 4, lines 33-36 of Schrier).

(M) Referring to claim 13, Schrier discloses further comprising the step of generating a prescription of the selected medication for a patient (col. 13, lines 6-8 of Schrier).

(N) Referring to claim 14, Schrier discloses further comprising the step of displaying a warning to the provider when the selected medication is known to possess medical dangers (col. 3, lines 29-34 of Schrier).

(O) Referring to claim 15, Schrier discloses further comprising the step of generating a selection whereby the provider may abandon the present prescription upon the warning (col. 7, lines 57-67 of Schrier; the Examiner interprets "delete" to be a form of "abandon").

(P) Referring to claim 16, Schrier discloses further comprising the step of generating dosing information by calculating the dose of the selected medication using information provided on a patient (col. 1, lines 32-33 & 52-55 of Schrier).

(Q) Referring to claim 17, Schrier discloses a computer based method of providing evidence-based information to a service provider that is in the process of making a decision as to a treatment regimen to be followed, the method comprising the steps of (Fig. 1, item 110, col. 4, lines 24-27, and col. 3, lines 36-39 of Schrier; the Examiner interprets "clinician" to be a form of "service provider" and "drug information and dosing recommendations" to be a form of "treatment regimen to be followed"):

a) prompting the provider to select a treatment regimen (col. 2, lines 23-33 of Schrier; the Examiner interprets "drug" to be a form of "treatment regimen");

(b) receiving the provider's selection of a treatment regimen (col. 2, lines 56-63 of Schrier); and

(c) in response to the provider's selective request, providing evidence-based information on the selected treatment regimen on a scaled basis (col. 3, lines 39-48 of Schrier; the Examiner interprets "publication references" to be a form of "evidence-based information").

(R) Referring to claim 18, Schrier discloses further comprising the step of:

after step (b) and before step (c), presenting a summary of the evidence-based information on the selected treatment regimen to assist the provider in selectively requesting the evidence-based information on a scaled basis (col. 29, line 63 – col. 30, line 1 of Schrier).

(S) Claim 19 repeats the same limitations of claim 7, and is therefore rejected for the same reasons given for that claim.

(T) Referring to claim 22, Schrier discloses further comprising the step of generating treatment instructions for a patient (col. 13, lines 6-16 of Schrier; the Examiner interprets "dosage" to be a form of "treatment instructions").

(U) Referring to claim 23, Schrier discloses wherein the treatment regimen is a medication (col. 1, lines 15-19 of Schrier; the Examiner interprets "drugs" to be a form of "medication").

(V) Referring to claim 24, Schrier discloses wherein the step of prompting the provider to select a medication comprises providing a list of medications (col. 5, lines 53-61 of Schrier).

(W) Claims 25-28 repeat the same limitations of claims 9-12, and are therefore rejected for the same reasons given for those claims.

(X) Referring to claim 29, Schrier discloses a computer-readable medium having computer-executable instructions for providing evidence-based information to a service provider that is in the process of making a decision as to a treatment regimen to be followed, the medium being adapted for carrying out the method of any one of claims 1 through 28 (col. 2, lines 56-63, col. 15, lines 40-46, and col. 3, lines 36-48 of Schrier).

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

(Y) Apparatus claims 30-31 and 34-36 repeat the subject matter of claims 1, 8, 12-13, and 16 as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Schrier in the above rejection of claims 1, 8, 12-13, and 16, it is readily apparent that the Schrier reference includes an apparatus to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claims 1, 8, 12-13, and 16 and incorporated herein.

(Z) Claims 32-33 repeat the same limitations of claims 9 and 11, and are therefore rejected for the same reasons given for those claims.

(AA) Referring to claim 37, Schrier discloses a computer system for providing evidence-based information to a service provider that is in the process of making a decision as to a treatment regimen to be followed, the system comprising (col. 3, lines 36-48 of Schrier):

a user interface including input means and output means (col. 2, lines 23-30 of Schrier);

a processing unit coupled to the user interface (col. 1, lines 58-64 of Schrier); and

a storage medium coupled to the processing unit (col. 2, lines 56-63 of Schrier);

wherein the processing unit being operable under control of program code stored in the storage medium to:

prompt the provider via the output means to select a medication;

receive the provider's selection of a medication via the input means; and

in response to the provider's selective request via the input means, provide evidence-based information of the selected medication on a scaled basis via the output means (col. 2, lines 23-33 and col. 3, lines 39-48 of Schrier).

(BB) Referring to claim 38, Schrier discloses wherein the processing unit is further operable to:

prompt the provider via the output means to select a condition of a patient to be treated (col. 8, lines 36-48 of Schrier); and

receive the provider's selection of a condition via the input means (col. 5, lines 45-52 of Schrier);

wherein the processing unit is operable to present a list of medications predetermined to be associated with the selected condition via the output means, from which list the provider is prompted to select one medication via the input means (col. 5, lines 53-61 of Schrier).

(CC) Referring to claim 39, Schrier discloses wherein the processing unit is further operable to generate a prescription of the selected medication for a patient including dosing information suited for the patient (col. 1, line 58 – col. 2, line 3 of Schrier; the Examiner interprets "prepared" to be form of "generate").

(DD) Referring to claim 40, Schrier discloses wherein the processing unit is further operable to calculate standard dosing based on the selected medication and physiological information of the patient (col. 2, lines 44-55 of Schrier; the Examiner interprets "height" and "weight" to be forms of "physiological information").

(EE) Referring to claim 41, Schrier discloses wherein the processing unit is further operable to prompt the provider via the output means to select standard dosing or manual dosing, wherein if the provider selects standard dosing via the input means, the unit calculates standard dosing of the selected medication, and if the provider selects manual dosing via the input means, the unit receives manual dosing that the provider enters via the input means (col. 14, lines 6-20 of Schrier).

(FF) Referring to claim 42, Schrier discloses wherein the processing unit is further operable to output the generated prescription including the dosing information via the output means (col. 13, lines 6-16 of Schrier).

(GG) Referring to claim 43, Schrier discloses wherein the processing unit is further operable to output the generated treatment instructions for a patient (col. 13, lines 6-16 of Schrier).

(HH) Claims 44-45 repeat the same limitations of claims 9 and 11, and are therefore rejected for the same reasons given for those claims.

(II) Referring to claim 46, Schrier discloses wherein the storage medium comprises a rules database, medication database, indications database, and rules notes database (col. 23, lines 48-57 of Schrier).

(JJ) Referring to claim 47, Schrier discloses wherein the rules database includes a predefined collection of evidence-based information, each piece of the evidence-based information comprising an article and being subdivided into a synopsis of the article, an abstract of the article, and the article itself, the synopsis, the abstract, and the article itself being independently retrievable from the rules database (col. 29, line 50 – col. 30, line 1 of Schrier).

(KK) Referring to claim 48, Schrier discloses wherein the medication database includes a predefined collection of records on common dosages, physical forms, and maximum dosages of medications (col. 2, lines 56-63 and col. 14, lines 6-20 of Schrier).

(LL) Referring to claim 49, Schrier discloses wherein the indication database includes a predefined collection of records on indications in association with medications that are used to treat the indications (col. 13, lines 6-16 of Schrier; the Examiner interprets "condition" to be a form of "indication").

(MM) Referring to claim 50, Schrier discloses wherein the rules notes database is adapted to store records of the provider's actions as indicated by the provider's input into the system using the input means (col. 14, line 65 – col. 15, line 9 of Schrier; the Examiner interprets "sends the current orders" to be a form of "provider's actions").

(NN) Referring to claim 51, Schrier discloses herein the storage medium further comprises a formulary database (col. 14, lines 6-20 of Schrier; the Examiner interprets "data file FrmStDose.dbf." to be a form of "database").

(OO) Referring to claim 55, Schrier discloses wherein the storage medium further comprises a patient database (col. 2, lines 44-55 of Schrier; the Examiner interprets "data files" to be a form of "database").

(PP) Referring to claim 56, Schrier discloses wherein the patient database includes a collection of patient records, each of the patient records comprising birth date, gender, weight, height, and medical history of each patient (col. 2, lines 44-55 of Schrier; the Examiner interprets "age" to be a form of "birth date", "sex" to be a form of "gender", and "clinical condition" to be a form of "medical history").

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier et al. (5,833,599) as applied to claim 17 above, and in view of Moukheibir (US 6,247,004 B1).

(A) Referring to claim 20, Schrier does not disclose further comprising the step of: providing a list of lab tests predetermined to be associated with the selected treatment regimen, from which the provider is prompted to select one or more lab tests.

Moukheibir discloses further comprising the step of: providing a list of lab tests predetermined to be associated with the selected treatment regimen, from which the provider is prompted to select one or more lab tests (col. 13, line 62 – col. 14, line 8 of Moukheibir).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Moukheibir within Schrier. The motivation for doing so would have been to display tests that would need to be performed in order to confirm a preliminary or trial diagnosis (col. 13, lines 62-65 of Moukheibir).

(B) Referring to claim 21, Schrier does not disclose further comprising the step of: providing a list of radiology examinations predetermined to be associated with the selected treatment regimen, from which the provider is prompted to select one or more radiology examinations.

Mouheibir discloses further comprising the step of: providing a list of radiology examinations predetermined to be associated with the selected treatment regimen, from which the provider is prompted to select one or more radiology examinations (col. 14,

lines 1-4 of Moukheibir; the Examiner interprets "imaging" to be a form of "radiology examinations").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Moukheibir within Schrier. The motivation for doing so would have been to display tests that would need to be performed in order to confirm a preliminary or trial diagnosis (col. 13, lines 62-65 of Moukheibir).

10. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier et al. (5,833,599) as applied to claims 37, 47, and 51 above, and in view of Edelson et al. (5,737,539).

(A) Referring to claim 52, Schrier does not disclose wherein the formulary database includes a predefined collection of records on formulas, intended uses, and methods of preparation of medications.

Edelson discloses wherein the formulary database includes a predefined collection of records on formulas, intended uses, and methods of preparation of medications (col. 1, lines 30-38 and col. 10, lines 60-66 of Edelson; the Examiner interprets "preferred medications for conditions" to be a form of "intended uses" and "formulation characteristics" to be a form of "methods of preparation of medications").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Edelson within Schrier. The motivation for doing so would have been to provide the physician user with a conveniently displayed,

concise selection of drugs for treating any particular condition (col. 12, lines 26-28 of Edelson).

11. Claims 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier et al. (5,833,599) as applied to claims 37 and 47 above, and in view of Becker et al. (US 2002/0019749 A1).

(A) Referring to claim 53, Schrier does not disclose wherein the storage medium further comprises a provider database.

Becker discloses wherein the storage medium further comprises a provider database (para. 117 of Becker; the Examiner interprets "directory" to be a form of "database").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Becker within Schrier. The motivation for doing so would have been to maintain a directory of health care providers and their contact information (para. 117, lines 9-11 of Becker).

(B) Referring to claim 54, Schrier does not disclose wherein the provider database includes a collection of provider records, each of the provider records comprising information selected from the group consisting of a name, Drug Enforcement Agency number, and email address of each provider.

Becker discloses wherein the provider database includes a collection of provider records, each of the provider records comprising name and email address of each provider (para. 117 of Becker).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Becker within Schrier. The motivation for doing so would have been to maintain a directory of health care providers and their contact information (para. 117, lines 9-11 of Becker).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches an enhanced medical treatment system (US 2003/0055679 A1); providing patient-specific drug information (US 6,317,719 B1); an integrated system and method for ordering and cumulative results reporting of medical tests (6,018,713); and a computer aided medical diagnostic method and apparatus (5,255,187).

Also included is provisional application 60/214,607, which is a priority document to applied reference, US 2002/0019749 A1 (Becket et al.).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (703) 305-0260. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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